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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,054	03/27/2000	NEAL ROSEN	-696-US	9414

7590

07/28/2003.

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EXAMINER

GOLDBERG, JEROME D

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 07/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/445,054

Applicant(s)

ROSEN ET AL.

Examiner

Jerome D Goldberg

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-- The MAILING DATE of this communication appears n the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 53 and 54 is/are allowed.
- 6) ☒ Claim(s) 49-51 and 55-57 is/are rejected.
- 7) ☒ Claim(s) 52 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Claim 52 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 53. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The restriction requirement set forth in paper no.7 is herein modified in that claims directed to the synergistic combination of prenyl-protein tranferase inhibitor with an antineoplastic agent selected from parlitaxel, epothilone A, epothilone B, desoxyepothilone A or desoxyepothilone B will be examined. This restricion requirement is herein made final.

Applicants are therefore required to reduce the scope of claim 49-51 and 55-57 to the scope of the elected combination.

Claims 49-51 and 55-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific antineoplastic agent which is a microtubule-stabilizing agent, does not reasonably provide enablement for the term "an antineoplastic agent which is a microtubule-stabilizing agent". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. ***.

The term "an antineoplastic agent which is a microtubule-stabilizing agent" in claims 49-51 and 55-57 lack clear exemplary support in the specification as filed.

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For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

1. Nature of invention.
2. State of prior art.
3. Level of ordinary skill in the art.
4. Level of predictability in the art.
5. Amount of direction and guidance provided by the inventor.
6. Existence of working examples.
7. Breadth of claims.
8. Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention:

The claims are drawn to methods and compositions for achieving a synergistic therapeutic effects in a mammal in need thereof employing a prenyl-protein transferase inhibitor and an antineoplastic agent which is a microtubule-stabilizing agent.

State of the prior art:

The prior art does not teach the combination together will produce a synergistic therapeutic effects.

Level of ordinary skill in the art:

The level of ordinary skill in the art is high. The genus set forth by the term "an antineoplastic agent which is a microtubule-stabilizing agent" encompasses a vast

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number of antineoplastic agent. These agent are employed to form a synergistic therapeutic effect.

Level of predictability in the art

There is little or no predictability in forming a synergistic therapeutic effect. Each combination must be showed.

Amount of direction and guidance provide by the inventor:

The specification on pages 294-300 gives direction in forming a test for the combination. The figures 1-12 and 23-27 give results of the antineoplastics agent which is a microtubule-stabilizing agent and compound A. These limited showings on one compound clearly would not support the large number of synergistic combination set forth in the above claims.

Existence of working examples:

The term "an antineoplastic agent which is a microtubule-stabilizing agent" encompasses a vast number of compounds. Applicants limited number of working examples will not support such a broad term. Moreover, being able to produce a synergistic therapeutic effect.

Breadth of claims:

The claims are extremely broad due to the vast number of possible combination that would produce a synergistic therapeutic effect.

Quantity of experimentation needed to make or use the invention based on the content of the disclosure:

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The skilled artisan would have a numerous amount of modifications to perform in order to obtain compounds as claimed.

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed process without undue experimentation.

Claim 52 is objected to as depend on a rejected claim.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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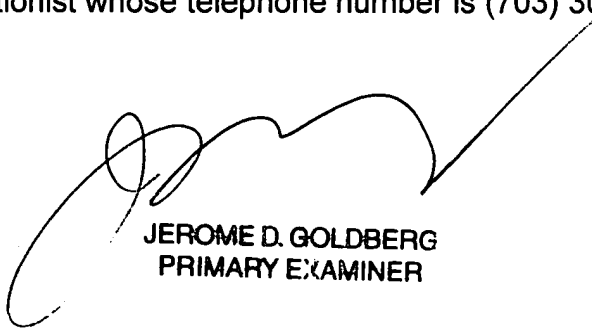
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner J. D. Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday-Thursday 9:00 A.M - 3:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Goldberg/tgd
July 15, 2003



JEROME D. GOLDBERG
PRIMARY EXAMINER